EUROPEAN
COMMISSION

Brussels, 15.11.2022
C(2022) 8356 (final)

COMMISSION IMPLEMENTING DECISION

of 15.11.2022

on the annual renewal of the conditional marketing authorisation for the orphan medicinal product for human use "Tecartus - brexucabtagene autoleucel", granted by Decision C(2020) 9284(final)

(Text with EEA relevance)

(ONLY THE DUTCH TEXT IS AUTHENTIC)

COMMISSION IMPLEMENTING DECISION

of 15.11.2022

on the annual renewal of the conditional marketing authorisation for the orphan medicinal product for human use "Tecartus - brexucabtagene autoleucel", granted by Decision C(2020) 9284(final)

(Text with EEA relevance)

(ONLY THE DUTCH TEXT IS AUTHENTIC)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[1], and in particular Article 10(2) and 14-a thereof,

Having regard to Commission Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council[2],

Having regard to the application submitted by Kite Pharma EU B.V., on 6 June 2022, under Article 6(2) of Regulation (EC) No 507/2006 with a view to the annual renewal of the conditional marketing authorisation for the medicinal product "Tecartus - brexucabtagene autoleucel",

Having regard to the opinion of the European Medicines Agency, formulated on 15 September 2022 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The medicinal product "Tecartus - brexucabtagene autoleucel", entered in the Union Register of Medicinal Products under the number EU/1/20/1492 and authorised by Commission Decision C(2020) 9284(final) of 14 December 2020, remains in compliance with the requirements of Article 14-a of Regulation (EC) No 726/2004 of the European Parliament and of the Council, and Regulation (EC) No 507/2006,

(2) The conditional marketing authorisation granted by Decision C(2020) 9284(final) should therefore be renewed.

(3) The Union Register of Medicinal Products should be updated.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 92, 30.3.2006, p. 6.

HAS ADOPTED THIS DECISION:

Article 1

The conditional marketing authorisation granted by Decision C(2020) 9284(final) of 14 December 2020 is renewed without amendments.

Article 2

The period of validity of the renewed authorisation shall be one year from 15 December 2022.

Article 3

This Decision is addressed to Kite Pharma EU B.V., Tufsteen 1, 2132 NT Hoofddorp, Nederland.

Done at Brussels, 15.11.2022

For the Commission

Sandra GALLINA
Director-General